Fourth, in the market for rifampin, which is used to treat tuberculosis, MMD markets Rifadin®. Hoechst was one of only a few firms developing a generic formulation of rifampin. Thus, the merger eliminates significant potential competition between these two products. The proposed Order requires Hoechst, within nine months, to divest either Rifadin® or the generic formulation of rifampin in development, to a Commission-approved acquirer.

The proposed Order also provides for the appointment of a trustee to assure that Hoechst appropriately completes the required divestitures. If Hoechst fails to divest any of the products within nine months, then the trustee's authority may be extended to include responsibility for accomplishing the required divestitures. The Order also requires Hoechst to provide technical assistance and advice to assist the purchaser(s) in obtaining FDA approval to manufacture and sell the divested products.

Under the provisions of the Order, Hoechst is also required to provide to the Commission a report of compliance with the divestiture provisions of the Order within sixty (60) days following the date the Order becomes final, and every sixty (60) days thereafter until Hoechst has completed the required divestitures. The Order also requires Hoechst to notify the Commission at least thirty (30) days prior to any change in the structure of Hoechst resulting in the emergence of a successor.

The purpose of this analysis is to facilitate public comment on the proposed Order, and it is not intended to constitute an official interpretation of the agreement and proposed Order or to modify in any way their terms.

Donald S. Clark,

Secretary.

[FR Doc. 95–23797 Filed 9–25–95; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Arthritis Advisory Committee

Date, time, and place. October 11, 1995, 8 a.m., Holiday Inn—Gaithersburg, Whetstone Ballroom, Two Montgomery Village Ave., Gaithersburg, MD, and October 12, 1995, 8:30 a.m., Holiday Inn—Silver Spring, Plaza Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Type of meeting and contact person. Open committee discussion, October 11, 1995, 8 a.m. to 1 p.m.; open public hearing, 1 p.m. to 2 p.m., unless public participation does not last that long; open committee discussion, 2 p.m. to 5 p.m.; open committee discussion, October 12, 1995, 8:30 a.m. to 9:30 a.m.; open public hearing, 9:30 a.m. to 10:30 a.m., unless public participation does not last that long; open committee discussion, 10:30 a.m. to 4:30 p.m.; Isaac F. Roubein or Kathleen Reedy, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Arthritis Advisory Committee, code 12532.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in arthritic conditions.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before September 29, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. On October 11, 1995, the committee will consider issues presented in a citizen petition submitted by the Health Research Group of Public Citizen (Docket No. 94P–0458/CP1). The petition requests that FDA remove from the market drug products containing piroxicam, a nonsteroidal anti-inflammatory drug (NSAID), stating that the drug presents a significantly higher risk of gastropathy than other drugs in its class. The committee will examine safety data for the drug and advise FDA on whether piroxicam should be withdrawn from the market, whether changes in the drugs' labeling should be made, or whether no action need be taken. On October 12, 1995, the committee will examine the adequacy of the current gastropathy warnings in labeling for the class of NSAID's.

Food Advisory Committee

Date, time, and place. October 11 and 12, 1995, 9 a.m., Disabled American Veterans, Denvel D. Adams National Service and Legislative Headquarters, 807 Maine Ave. SW., Washington, DC. Seating for this meeting is limited. If you plan to attend, please call a contact person listed below to reserve a seat.

Type of meeting and contact person. Open committee discussion, October 11, 1995, 9 a.m. to 4 p.m.; open public hearing, October 12, 1995, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 4 p.m.; Lynn A. Larsen, Center for Food Safety and Applied Nutrition (HFS–5), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4727, or Catherine M. DeRoever, Advisory Committee Staff (HFS–22), 202–205–4251, FAX 202–205–4970, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Food Advisory Committee, code 10564.

General function of the committee. The committee provides advice on emerging food safety, food science, and nutrition issues that FDA considers of primary importance in the next decade.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in

writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person by close of business September 29, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments. If necessary, comments may be limited to 5 minutes.

Open committee discussion. A working group will consider the significance and extent of the serious adverse events associated with the consumption of food products containing a source of ephedrine alkaloids, including ephedrine, pseudoephedrine, and norpseudoephedrine from *Ephedra sinica* Stapf. and other related species (e.g., Ma huang and Chinese ephedra). More detailed information regarding the meeting agenda that may become available prior to the meeting and on the availability of background materials will be provided to the public via the 800 number given above.

Psychopharmacologic Drugs Advisory Committee

Date, time, and place. October 16, 1995, 8:30 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Michael A. Bernstein, Center for Drug Evaluation and Research (HFD–120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5521, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Psychopharmacologic Drugs Advisory Committee, code 12544.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of psychiatry and related fields.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before October 9, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will discuss the safety and effectiveness of REMERON® (mirtazapine), new drug application (NDA) 20–415, Organon, Inc., for use in the treatment of depression.

Oncologic Drugs Advisory Committee

Date, time, and place. October 16 and 17, 1995, 8 a.m., Quality Hotel, Maryland Room, 8727 Colesville Rd., Silver Spring, MD.

Type of meeting and contact person. Open public hearing, October 16, 1995, 8 a.m. to 8:30 a.m., unless public participation does not last that long; open committee discussion, 8:30 a.m. to 5 p.m.; open public hearing, October 17, 1995, 8 a.m. to 8:30 a.m., unless public participation does not last that long; open committee discussion, 8:30 a.m. to 5 p.m.; Adele S. Seifried, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4695, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Oncologic Drugs Advisory Committee, code 12542.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in treatment of cancer.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before October 12, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. On October 16, 1995, the committee will discuss: (1) NDA 20–497, Fareston® (toremifene, Orion Corp.) for treatment of advanced breast cancer in postmenopausal women and (2) NDA 20–541, Arimidex® (anastrozole, Zeneca Pharmaceuticals) as ''a selective aromatase inhibitor for the treatment of postmenopausal women with advanced breast cancer who develop progressive disease while receiving tamoxifen.'' On October 17, 1995, the committee will discuss: (1) NDA 20–449, Taxotere® (docetaxel, Rhone-Poulenc Rorer) for treatment of ''patients with locally advanced or metastatic breast carcinoma in whom previous therapy has failed; prior therapy should have included an anthracycline unless clinically contraindicated,'' and (2) product license application 91–0209, CEA–Scan™ (arcitumomab, Immunomedics, Inc.) ''for diagnostic imaging in pre-surgical patients who are being considered for resection of recurrent/metastatic colorectal cancer and, in combination with standard diagnostic modalities (SDM), for more accurate localization of carcinoembryonic antigen (CEA)-producing colorectal cancers.''

Ophthalmic Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. October 19 and 20, 1995, 8:30 a.m., Holiday Inn—Gaithersburg, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the Holiday Inn—Gaithersburg. Attendees requiring overnight accommodations may contact the hotel at 301–948–8900 and reference the FDA Ophthalmic Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Ed Rugenstein, Sociometrics, Inc., 8300 Colesville Rd., suite 550, Silver Spring, MD 20910, 301–608–2151. The availability of appropriate accommodations cannot be assured unless prior notification is received.

Type of meeting and contact person. Open public hearing, October 19, 1995, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; open public hearing, October 20, 1995, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Sara M. Thornton, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Ophthalmic Devices Panel, code 12396.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the

committee. Those desiring to make formal presentations should notify the contact person before September 30, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. On October 19, 1995, the committee will discuss general issues relating to premarket approval applications (PMA's) for retinal tamponades used for the treatment of complicated retinal detachments. On October 20, 1995, the committee will discuss general issues relating to a PMA for an excimer laser for photorefractive keratectomy. General updates will include the redraft of the myopia refractive laser guidance document.

Cardiovascular and Renal Drugs Advisory Committee

Date, time, and place. October 19 and 20, 1995, 9 a.m., National Institutes of Health, Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. Parking in the Clinical Center visitor area is reserved for Clinical Center patients and their visitors. If you must drive, please use an outlying lot such as Lot 41B. Free shuttle bus service is provided from Lot 41B to the Clinical Center every 8 minutes during rush hour and every 15 minutes at other times.

Type of meeting and contact person. Open public hearing, October 19, 1995, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5 p.m.; open committee discussion, October 20, 1995, 9 a.m. to 5 p.m.; Joan C. Standaert, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 419–259–6211, or Valerie M. Mealy, Advisors and Consultants Staff, 301–443–4695, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Cardiovascular and Renal Drugs Advisory Committee, code 12533.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in cardiovascular and renal disorders.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before October 6, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. On October 19, 1995, the committee will discuss NDA: 20–491, ibutilide (Convert®, The Upjohn Co.), for conversion of atrial flutter and atrial fibrillation, and NDA 20–546, vasoprost (Alprostadil® Schwarz-Pharma Kremers Urban) for severe peripheral arterial occlusive disease to reduce the incidence of leg amputations in nondiabetic patients. On October 20, 1995, the committee will discuss ''Anti-hypertensive Agents; Guidelines for Therapy.''

Joint Meeting of the Anti-Infective Drugs Advisory Committee and the Gastrointestinal Drugs Advisory Committee

Date, time, and place. October 26, 1995, 8:30 a.m., Holiday Inn—Gaithersburg, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Ermona B. McGoodwin or Valerie Mealy, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Anti-Infective Drugs Advisory Committee, code 12530.

General function of the committees. The Anti-Infective Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders. The Gastrointestinal Drugs Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in gastrointestinal diseases.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before October 20, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committees will meet jointly to discuss treatment of *Helicobacter pylori* to reduce peptic ulcer recurrence and to discuss resistance implications of widespread *Helicobacter pylori* treatment.

Anti-Infective Drugs Advisory Committee

Date, time, and place. October 27, 1995, 8:30 a.m., Holiday Inn—Gaithersburg, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Ermona B. McGoodwin or Mary Elizabeth Donahue, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Anti-Infective Drugs Advisory Committee, code 12530.

General function of the committee. The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before October 20, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will discuss the diagnosis of *Helicobacter pylori* related gastrointestinal disease and resistance implications of widespread *Helicobacter pylori* treatment.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee

discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: September 19, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 95–23738 Filed 9–25–95; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[BPD–824–N]

Medicare Program; Update of Ambulatory Surgical Center (ASC) Payment Rates Effective for Services On or After October 1, 1995

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice implements section 1833(i)(2)(C) of the Social Security Act, which mandates an automatic inflation adjustment to Medicare payment amounts for ambulatory surgical center (ASC) facility services during the years when the payment amounts are not updated based on a survey of the actual audited costs incurred by ASCs.

EFFECTIVE DATE: The payment rates contained in this notice are effective for services furnished on or after October 1, 1995.

Copies: To order copies of the Federal Register containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $8. As an alternative, you can view and photocopy the Federal Register document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the Federal Register.

FOR FURTHER INFORMATION CONTACT: Joan Haile Sanow, (410) 786–5723.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) provides that benefits under the Medicare Supplementary Medical Insurance program (Part B) include services furnished in connection with those surgical procedures that, under section 1833(i)(1)(A) of the Act, are specified by the Secretary and are performed on an inpatient basis in a hospital but that also can be performed safely on an ambulatory basis in an ambulatory surgical center (ASC), in a rural primary care hospital, or in a hospital outpatient department. To participate in the Medicare program as an ASC, a facility must meet the standards specified under section 1832(a)(2)(F)(i) of the Act and 42 CFR 416.25, which set forth basic requirements for ASCs.

Generally, there are two elements in the total charge for a surgical procedure: A charge for the physician's professional services for performing the procedure, and a charge for the facility's services (for example, use of an operating room). Section 1833(i)(2)(A) of the Act authorizes the Secretary to pay ASCs a prospectively determined rate for facility services associated with covered surgical procedures. ASC facility services are subject to the usual Medicare Part B deductible and coinsurance requirements. Therefore, participating ASCs are paid 80 percent of the prospectively determined rate for facility services, adjusted for regional wage variations. This rate is intended to represent our estimate of a fair payment that takes into account the costs incurred by ASCs generally in providing the services that are furnished in connection with performing the procedure. Currently, this rate is a standard overhead amount that does not include physician fees and other medical items and services (for example, durable medical equipment for use in the patient's home) for which separate payment may be authorized under other provisions of the Medicare program.

We have grouped procedures into nine groups for purposes of ASC payment rates. The ASC facility payment for all procedures in each group is established at a single rate